UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 01-6194-CIV-DIMITROULEAS

ANDRX PHARMACEUTICALS, INC.,	)
	)
Plaintiff,	)
	)
v.	)
	)
BIOVAIL CORPORATION INTERNATIONAL,	)
	)
Defendant,	)
	)
and	)
	)
TOMMY G. THOMPSON, Secretary, U.S. Department of Health and Human Services, BERNARD A. SCHWETZ, D.V.M., PhD., Acting Principal Deputy Commissioner, U.S. Food and Drug Administration, and U.S. FOOD AND DRUG ADMINISTRATION,	)
	)
Additional Defendants.	)

FEDERAL DEFENDANTS' NOTICE OF CHANGE IN POSITION

The purpose of this Notice is to inform the Court of a new development in the above-referenced case that has required the federal defendants to modify their position with respect to the listing of the '463 patent at issue in this case.

As the Court is aware, on Monday, February 26, the federal defendants in this case filed a motion to dismiss and a memorandum in support of the motion and in opposition to Andrx's motion for preliminary injunction. FDA argued that Andrx had failed to state any claim against the federal

defendants and that Andrx had failed to show that FDA's actions in listing patent '463, or its interpretation of the relevant statutory provisions and regulations, was unreasonable.

In particular, FDA explained that the agency listed the '463 patent pursuant to the statute and regulations based on Biovail's declaration that the patent covers a formulation of Tiazac® that is currently approved by FDA. See Memorandum of Federal Defendants at 6-9 & Ex. B. Because Andrx challenged this listing in accordance with the FDA regulations, the agency sought confirmation from Biovail that the '463 patent "claims the drug product and formulation approved in the Tiazac® NDA [new drug application]." Id. at 8 & Exhibits C, D. After Andrx filed the current lawsuit and Biovail had not responded to the agency's confirmation request, FDA asked Biovail to notify the agency if it was mistaken in its understanding that the '463 patent claimed Tiazac®. Id. at 9-10 & Ex. E. Biovail did not respond to the agency's request. Thus, based on Biovail's declaration and its handling of FDA's confirmation requests, Biovail appeared to indicate that the '463 patent claimed the approved drug product Tiazac®.

On Monday, February 26, however, Biovail filed its memorandum in opposition to Andrx's motion for preliminary injunction. FDA has carefully reviewed Biovail's statements in its memorandum and the facts alleged in its supporting declarations. In particular, Biovail stated that it recently revised its manufacturing process for Tiazac®, "so that 1.1 percent (by weight) of the diltiazem hydrochloride [active ingredient] is now outside the coated beads within each capsule." See Biovail Memorandum at 3-4; Declaration of Paul Maes ("Maes Declaration") at ¶¶ 4, 5. Biovail further asserted that the New Drug Application ("NDA") for Tiazac®, approved by FDA in 1995, is "broad enough to cover *both* versions of the product, *i.e.*, whether produced using the old manufacturing method or the new one" and that Biovail would advise FDA of this change in its next annual report. See Biovail Memorandum at 4; Maes Declaration at ¶¶ 6, 7; Declaration of John R.

Markus ("Markus Declaration") at ¶¶ 6.

FDA was unaware of this change in the manufacturing and formulation of Tiazac® until Biovail's revelation in its declarations and supporting memorandum. Contrary to Biovail's assertions, FDA believes that the changes in formulation and manufacturing of Tiazac® described by Biovail are not in fact covered by the approved NDA for Tiazac®. Based on the information submitted by Biovail to this Court, FDA has preliminarily concluded that Biovail must file a supplement to its NDA for agency approval before it can distribute the drug product with the revised manufacturing processes and new formulation. Furthermore, it now appears from Biovail's newly submitted declarations that the '463 patent does not claim the drug product as originally approved, but only claims the product in its revised (and unapproved) form. Thus, by virtue of Biovail's own statements, FDA is now of the view that the '463 patent does not claim the approved drug product as required by the statute and therefore cannot be listed in the Orange Book for Tiazac®.

It is important to note that FDA's position does not in any way conflict with the approach set forth in its supporting memorandum. As FDA explained, once an NDA holder provides the required information in its declaration for filing a patent with the agency, FDA then lists that information in the Orange Book. To the extent the NDA holder and applicant with an Abbreviated New Drug Application ("ANDA") disagree about whether the patent actually "claims" the approved drug product at issue under patent law doctrine, the private parties can resolve this patent issue in litigation without FDA as a party. See Memorandum of Federal Defendants at 14-16. However, where an NDA holder in a lawsuit makes subsequent representations that show on their face that the patent which allegedly claims the approved drug product at issue actually claims a different, unapproved, formulation of the product, then it is proper and necessary for the agency to reconsider the listing of the patent.

Because the issue of the legality of the listing of the '463 patent is currently before this Court, FDA has deferred taking any action with respect to the '463 patent so as not to interfere with the Court's consideration of this issue and in order to permit all parties to be heard. The government will be prepared to explain the agency's position in more detail at the hearing and to file supplemental briefs, if necessary. Furthermore, FDA is aware that there are other issues raised by the parties, such as jurisdiction, that the Court may wish to consider before reaching the merits of Andrx's claims against Biovail concerning the listing of the patent. Thus, FDA will defer to the Court concerning the best means of handling this matter in the context of the litigation.

Respectfully submitted,

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February 28, 2001